UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,022	06/23/2003	Jonathan McKinno Collins	1700.129	1021

21176 7590 03/15/2006

SUMMA, ALLAN & ADDITON, P.A.
11610 NORTH COMMUNITY HOUSE ROAD
SUITE 200
CHARLOTTE, NC 28277

EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/604,022	COLLINS ET AL.	
	Examiner	Art Unit	
	Marcela M. Cordero Garcia	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) *13-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 62-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Please also note that Applicant's amendment of October 24, 2005 is not compliant because the withdrawn claims are not stated therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (J Org Chem 1992, citation 6 in the IDS of June 7, 2004) in view of Daga et al. (Tetrahedron Letters, 2001)

Yu et al. teach a process for the solid phase synthesis of peptides, which comprises:

(a) deprotecting a first amino acid linked to a solid phase resin by removing protective first chemical groups;

(b) activating chemical groups on a second amino acid to prepare the second amino acid for coupling with the first amino acid;

c) coupling the activated second amino acid to the deprotected first amino acid to form a peptide from the first and second amino acids; and

(d) accelerating at least the coupling step by applying microwave energy during the coupling step. (see, e.g., page 4782-4784, Figures 1-2 and Scheme 1).

Yu et al. do not expressly teach accelerating the deprotecting step by applying microwave energy during the deprotecting step.

Daga et al. teach a process for the solid phase synthesis of peptides, which comprises accelerating the deprotecting step by applying microwave energy during the deprotecting step. (See, e.g., abstract, page 5193, column 1, lines 14-34 and column 2, lines 12-16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the microwave method of Yu et al. by also accelerating the deprotecting step during peptide synthesis with microwaves as taught by Daga et al. (See, e.g., abstract, page 5193, column 1, lines 14-34 and column 2, lines 12-16), The skilled artisan would have been motivated to do so because it was known in the art that microwave-driven synthetic methods --in comparison to conventional heating methods-- substantially accelerate reactions and save time (e.g., Yu et al. page 4781, column 1, lines 13-15), provide higher yields and reduce racemization (e.g., Daga et al. page 5193, column 1, lines 13-15).

Thus, the invention as a whole is prima facie obvious over the references.

Claims 1-12 and 62-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (J Org Chem 1992, citation 6 in the IDS of June 7, 2004) in view of Daga et al. (Tetrahedron Letters, 2001) in view of Stadler et al. (Eur J Org Chem, 2001) and in view of Santagada et al. (Tetrahedron Letters, 2001, citation 4 in the IDS of November 8, 2004).

Yu et al. teach a process for the solid phase synthesis of peptides, which comprises:

(a) deprotecting a first amino acid linked to a solid phase resin by removing protective first chemical groups;

(b) activating chemical groups on a second amino acid to prepare the second amino acid for coupling with the first amino acid;

c) coupling the activated second amino acid to the deprotected first amino acid to form a peptide from the first and second amino acids; and

(d) accelerating at least the coupling step by applying microwave energy during the coupling step. (see, e.g., page 4782-4784, Figures 1-2 and Scheme 1).

Yu et al. do not expressly teach accelerating the deprotecting step by applying microwave energy during the deprotecting step, maintaining the peptide in a single vessel during the process proactively cooling the vessel and its contents during application of microwave energy, cleaving the peptide from the resin applying microwave energy, deprotecting side chains of the peptide, spiking the microwave energy, using phosphorium activators, uranium activators, HATU,

HBTU, PyBOP, PyAOP or HOBT, monitoring the temperature of the vessel and moderating the applied power accordingly.

Daga et al. teach a process for the solid phase synthesis of peptides, which comprises accelerating the deprotecting step by applying microwave energy during the deprotecting step. (See, e.g., abstract, page 5193, column 1, lines 14-34 and column 2, lines 12-16).

Stadler et al. teach cleaving various molecules including carboxylic acids from resins by applying microwave energy, spiking the microwave energy, proactively cooling the vessel and monitoring the temperature of the vessel, moderating the applied power accordingly (see, e.g., page 922, column 2, paragraph 2; page 923 and Scheme 2, page 924, columns 1-2).

Santagada et al. teach using PyBOP/HOBt and HBTU/HOBt activators in a microwave method for peptide synthesis (see, e.g., pages 5171-5173).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the microwave method of Yu et al. by also accelerating the deprotecting step during peptide synthesis with microwaves as taught by Daga et al. (See, e.g., abstract, page 5193, column 1, lines 14-34 and column 2, lines 12-16), by accelerating the cleavage from the solid-support resin as taught by Stadler et al. (See, e.g., page 922, column 2, paragraph 2; page 923 and Scheme 2, page 924, columns 1-2), and by using activators such as PyBOP/HOBt and HBTU/HOBt during microwave activation, spiking the microwave energy, proactively cooling the vessel and monitoring the temperature of the vessel, moderating the applied power accordingly, as taught by Santagada

et al. (See, e.g., pages 5171-5173). The skilled artisan would have been motivated to do so because it was known in the art that microwave-driven synthetic methods --in comparison to conventional heating methods-- substantially accelerate reactions and save time (e.g., Yu et al. page 4781, column 1, lines 13-15), provide higher yields (e.g., Santagada et al. abstract), and reduce racemization (e.g., Daga et al. page 5193, column 1, lines 13-15). The adjustment of particular conventional working conditions (e.g., maintaining the peptide in a single vessel during the process and deprotecting also side chains of the peptide) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the references.

Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erdelyi et al. (Synthesis 2002, citation 7 in the IDS of June 7, 2004) in view of Daga et al. (Tetrahedron Letters, 2001).

Erdelyi et al. teach a process for the solid phase synthesis of peptides, which which comprises:

(a) deprotecting a first amino acid linked to a solid phase resin by removing protective first chemical groups;

(b) activating chemical groups on a second amino acid to prepare the second amino acid for coupling with the first amino acid;

c) coupling the activated second amino acid to the deprotected first amino acid to form a peptide from the first and second amino acids; and

(d) accelerating at least the coupling step by applying microwave energy during the coupling step. (see, e.g., pages 1592-1594).

Erdelyi et al. do not expressly teach accelerating the deprotecting step by applying microwave energy during the deprotecting step. (see, e.g., page 1592, column 2, lines 13-15).

Daga et al. teach a process for the solid phase synthesis of peptides, which comprises accelerating the deprotecting step by applying microwave energy during the deprotecting step. (See, e.g., abstract, page 5193, column 1, lines 14-34 and column 2, lines 12-16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the microwave method of Yu et al. by also accelerating the deprotecting step during peptide synthesis with microwaves as taught by Daga et al. (See, e.g., abstract, page 5193, column 1, lines 14-34 and column 2, lines 12-16), The skilled artisan would have been motivated to do so because it was known in the art that microwave-driven synthetic methods --in comparison to conventional heating methods-- substantially accelerate reactions, save time (e.g., Erdelyi et al. page 1592, abstract), provide higher yields and reduce racemization (e.g., Daga et al. page 5193, column 1, lines 13-15 and Erderlyi et al., abstract). The adjustment of particular conventional working conditions (e.g., maintaining the peptide in a single vessel during the process and deprotecting also side chains of the peptide) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the references.

Claims 1-12 and 62-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erdelyi et al. (Synthesis 2002, citation 7 in the IDS of June 7, 2004) in view of Daga et al. (Tetrahedron Letters, 2001) and in view of Stadler et al. (Eur J Org Chem, 2001).

Erdelyi et al. teach a process for the solid phase synthesis of peptides, which which comprises:

(a) deprotecting a first amino acid linked to a solid phase resin by removing protective first chemical groups;

(b) activating chemical groups on a second amino acid to prepare the second amino acid for coupling with the first amino acid;

c) coupling the activated second amino acid to the deprotected first amino acid to form a peptide from the first and second amino acids; and

(d) accelerating at least the coupling step by applying microwave energy during the coupling step. (see, e.g., pages 1592-1594).

Erdelyi et al. do not expressly teach accelerating the deprotecting step by applying microwave energy during the deprotecting step, maintaining the peptide in a single vessel during the process, proactively cooling the vessel and its contents during application of microwave energy, cleaving the peptide from the resin applying microwave energy, deprotecting side chains of the peptide, spiking the microwave energy and/or monitoring the temperature of the vessel).

Daga et al. teach a process for the solid phase synthesis of peptides, which comprises accelerating the deprotecting step by applying microwave energy during the deprotecting step. (See, e.g., abstract, page 5193, column 1, lines 14-34 and column 2, lines 12-16).

Stadler et al. teach cleaving various molecules including carboxylic acids from resins by applying microwave energy, spiking the microwave energy, proactively cooling the vessel and monitoring the temperature of the vessel (see, e.g., page 922, column 2, paragraph 2; page 923 and Scheme 2, page 924, columns 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the microwave method of Yu et al. by also accelerating the deprotecting step during peptide synthesis with microwaves as taught by Daga et al. (See, e.g., abstract, page 5193, column 1, lines 14-34 and column 2, lines 12-16), by accelerating the cleavage from the solid-support resin, by using activators such as PyBOP/HOBt and HBTU/HOBt during microwave activation, spiking the microwave energy, proactively cooling the vessel and monitoring the temperature of the vessel, moderating the applied power accordingly, as taught by Stadler et al. (See, e.g., page 922, column 2, paragraph 2; page 923 and Scheme 2, page 924, columns 1-2). The skilled artisan would have been motivated to do so because it was known in the art that microwave-driven synthetic methods --in comparison to conventional heating methods-- substantially accelerate reactions and save time (Erdelyi et al. abstract and column 1, last paragraph), provide higher yields and reduce racemization

(e.g., Daga et al. page 5193, column 1, lines 13-15). The adjustment of particular conventional working conditions (e.g., maintaining the peptide in a single vessel during the process and deprotecting also side chains of the peptide) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the references.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 02/06

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600